GM plant environmental risk assessment: pros and cons of different approaches

Dr. Hartmut Meyer
ENSSER, Scientific Coordinator

EFSA Consultative Workshop on the Draft Guidance on Selection of Comparators for the Risk Assessment of GM Plants
”Principles for the application of substantial equivalence to the assessment of foods from organisms developed by the application of biotechnology:

1. If the new or modified food or food component is determined to be substantially equivalent to an existing food, then further safety or nutritional concerns are expected to be insignificant.

OECD 1993a, p. 11-12
Concept of Substantial Equivalence in Relation to Risk Assessment

2. *Where a product is determined not to be substantially equivalent, the identified differences should be the focus of further evaluations;*

3. *Where there is no basis for comparison of a new food or food component, ... then the new food or food component should be evaluated on the basis of its own composition and properties."

OECD 1993a, p. 11-12
Concept of Familiarity in Relation to Risk Assessment

”The levels and variation for characteristics in the genetically modified organism must be within the natural range of variation for those characteristics considered in the comparator”

Concept of Familiarity in ERA
- Broad Range of Comparators

“Familiarity comes from the knowledge and experience available for conducting a risk/safety analysis prior to scale-up of any new plant line or crop cultivar in a particular environment. ...

- ... lines of the crop plant developed with more traditional techniques ...

- ... other plant lines developed by the same technique ...“

OECD 1993b, p.28
"The concept of substantial equivalence has never been properly defined; the degree of difference between a natural food and its GM alternative before its ‘substance’ ceases to be acceptably ‘equivalent’ is not defined anywhere, nor has an exact definition been agreed by legislators."

Millstone et al. 1999, p. 525
"Hence, the concept of a history of safe use from food safety relates less easily to ERA, in which environmental harm is measured. ... Second, for ERA, it makes little practical sense for the equivalence limits to be based on the natural variation of extraneous varieties."

Perry et al. 2009, p.68
Concept of Familiarity - No Recognition in GMO ERA

Cartagena Protocol on Biosafety:
Concept of Familiarity was introduced in 1996 (BSWG-1), discussed in BSWG-2 and BSWG-3, finally rejected in 1998 (BSWG-4)

Directive 2001/18/EC:
no mentioning of the Concept of Familiarity
Current Legal Approaches in ERA
- Comparison with Parental Organisms

”Risks associated with living modified organisms ... should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.”


”In accordance with the precautionary principle, the following general principles should be followed when performing the e.r.a.:
- identified characteristics of the GMO and its use which have the potential to cause adverse effects should be compared to those presented by the non-modified organism from which it is derived and its use under corresponding situations; ...”

EC 2001, Annex II B
"The concept of substantial equivalence is a key step in the safety assessment process. However, it is not a safety assessment in itself; rather it represents the starting point which is used to structure the safety assessment of a new food relative to its conventional counterpart."

CAC 2003, para 13

"Whilst substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself."

EC 2003, Recital 6
”Statistically significant differences between the GM plant and its appropriate comparators should be assessed specifically with respect to their **biological relevance** and potentially hazardous environmental implications. The outcome of the comparative safety assessment [...] will thus further structure the ERA.

.... The underlying assumption of the comparative assessment for GM plants is that the biology of traditionally cultivated plants from which the GM plants have been derived, and the appropriate comparators is well known. To this end the **concept of familiarity** was developed by the OECD.”  

EFSA 2010
... by Renaming?
Recommendations

- Abandonment of concept of comparative safety assessment and concept of familiarity applied prior to ERA
- Strict application of the 2001/18 general principle "comparison of GMO with parental organisms" within ERA
- Development of a risk assessment "per se" at least when there are no appropriate parental organisms
Recommendations

➢ Establishment of scientific criteria for judging statistically significant differences in unintended effects between the GMO and the biological comparator as biological and ecological irrelevant

➢ Establishment of scientific criteria for appropriate choice of receiving environments as environmental comparators for the determination of harm
"Let me draw an example with the strategy for risk assessment, which is often somewhat confusingly termed ‘substantial equivalence.’ [...] In actual fact, the comparative approach followed in the risk assessment strategy is exactly the opposite.

A thorough comparison between a GMO and a conventional safe counterpart allows the identification of all the differences created by the genetic modification. [...] All these differences are then investigated in detail with respect to possible toxicological, environmental, allergenic or nutritional aspects. ”

Dalli 2011
ENSSER notes with interest that Commissioner Dalli has not used the wording "comparative safety assessment" as suggested as new principle in ERA.

ENSSER is determined to engage critically and constructively in the debate on reforming the EU system for GMO and GM food risk assessment.

Thank you!
References

Dalli (2011) GMOs : towards a better, more informed decision-making process
OECD (1993a) Safety evaluation of foods derived by modern biotechnology – Concepts and principles
OECD (1993b) Safety considerations for biotechnology: Scale-up of crop plants